

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Scott Smith and Christopher Brian Brodeur
Application No.:	10/643,527
Filed:	August 19, 2003
For:	[Improved] Composite Vascular Graft
Examiner:	Lindsey Michele Bachman
Group Art Unit:	3734

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2Q-14457-US02

REPLY BRIEF

This is a Reply Brief being filed in response to the Examiner's Answer mailed February 2, 2010.

Claims 1-23 have been presented in the application. Claims 1-14 and 17 have been canceled. Claims 15, 16 and 18-23 are pending in the application and have been twice or finally rejected. Claims 15, 16 and 18-23 are being appealed. No amendments were made subsequent to the Final Office Action.

A Notice of Appeal was filed in this case on September 28, 2009. The fees required under § 1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

Reply to Examiner's Answer

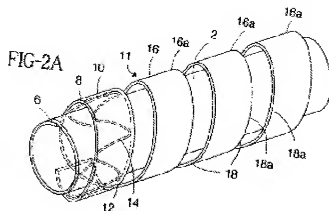
Independent claim 15 of the present application is directed to a method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite wherein a polytetrafluoroethylene (PTFE) tape strip is combined with a distensible support structure to form an assembly strip and the assembly strip is combined with a substantially continuous inner tubular body support by wrapping the assembly strip about the inner tubular body support in a nonoverlapping pattern, such that the distensible support structure is placed in direct contact with both the tubular inner body and the tape strip completely overlies the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components.

Claims 16, 18 and 21-23 depend therefrom.

Independent claim 19 is directed to a method of making an implantable intraluminal stent/graft composite prosthesis including, inter alia, wrapping a stent directly against a continuous ePTFE tubular inner body, in a non-overlapping relationship and wrapping an ePTFE strip about the tubular inner body and stent, to overlie the stent.

Independent claim 20 is directed to a method of making an implantable intraluminal stent/graft prosthesis including, inter alia, assembling a stent with an ePTFE strip to make an assembly strip with a stent side and an ePTFE strip side and wrapping the assembly strip around the inner body in non-overlapping relationship, such that the stent side is placed directly against the ePTFE tubular inner body.

An example of the embodiment recited in these claims is found from FIG. 2A of the present application:



As can be clearly seen from FIG. 2A, the stent 14 is wrapped directly against a continuous ePTFE tubular inner body 2 in a non-overlapping relationship and an outer ePTFE strip 16 about the tubular inner body 2 and stent 14, to overly the stent such that the stent side is placed in direct contact with the inner tubular body 2.

“Bonding of the ePTFE layers without an adhesive may take place by such methods as laminating, or sintering of the prosthesis.” See paragraph [0043].

The rejection of claims 15, 16 and 18-23 under 35 U.S.C. 103(a) as being obvious over Golds et al. (US Patent 6,001,125) in view of Banas et al. (6,264,684) has been maintained.

It is asserted in the Examiner’s Answer, Response to Arguments, that:

Appellant argues that Gold in the embodiment of Figures 4 and 5, Gold teaches an inner tubular member and an outer tubular member which are separated by an ePTFE tape strip. In the embodiment of Figures 6-8, Gold teaches that the inner tubular member and outer tubular member can be separated by a stent. Appellant states that Gold does not teach the use of both a strip and stent in the same embodiment.

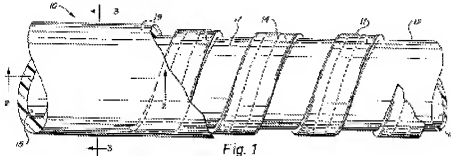
Gold’s embodiment of Figure 4 and 5 was not referenced in the rejection. Examiner agrees with Appellant’s assertion that Gold does not teach an embodiment with a strip and a stent, however, the rejection is based on the combination of Gold in view of Banas. Examiner maintains that it would be obvious to form the outer tubular member (22) and distensible member (36) of Gold into an assembly strip, as taught by Banas, rather than use

them in their tubular form. Banas teaches this is advantageous for the purpose of controlling and customizing the location of the stent structure on the inner tubular member (column 10, line 56 to column 11 line 18). In light of this teaching, it would be obvious to apply the teachings of Banas '684 to the Gold '125 device.

Examiner's Answer, pp. 4-5

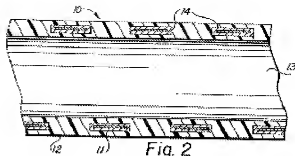
However, regardless as to what embodiment of Golds et al. is being employed in the rejection, the combination of Golds et al. and Banas et al. still fails to lead one of ordinary skill in the art to the embodiments recited in Applicants' independent claims.

Banas et al.'s device is most clearly represented by FIG. 1:



A support member 14 at least partially covered by a polymeric cladding 11 is circumferentially disposed about and joined to the abluminal wall surface of the support substrate 12 such as be helically winding the polymeric clad support member 14 about the tubular substrate 12.

A second tubular substrate 19 is optionally provided over the inner tubular substrate 12 and the polymer clad support member 14 which fills in the gaps that exist from winding the polymer clad support member 14 about the inner tubular member as shown in FIG. 2:

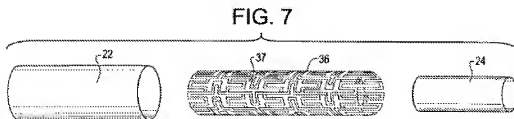


See also FIGS. 4A-4C.

The wire winding disclosed by Banas et al. is always at least partially clad with another polymer. The stent is not placed in direct contact with the inner tubular member. See Summary of the Invention, 4th paragraph.

Golds et al. disclose a PTFE vascular prosthesis including first and second ePTFE tubular structures wherein the second ePTFE tubular structure is disposed externally about the first ePTFE tubular structure to define a distinct porosity change between the first and second PTFE tubular structure and a tubular diametrically deformable intermediate layer interposed between the first and second PTFE tubular structure. See Abstract and claim 1.

The Golds et al. assembly is illustrated by FIG. 7 reproduced below:



The intermediate layer may be either a stent or a helical wrap of ePTFE tape.

In the rejection of Applicant's claims, it is proposed that both the stent and the outer tubular member are replaced by the polymer clad wire winding.

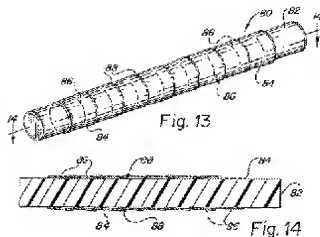
However, because the wire winding is polymer clad, it is not in direct contact with the inner ePTFE tubular member disclosed by Golds et al.

The combination simply does not produce the embodiments recited in Applicant's independent claims 1 and 20 wherein the support structure is in direct contact with an inner tubular ePTFE member and the support structure is wrapped with an ePTFE tape.

The Banas et al. polymer clad wire winding excludes direct contact of the wire winding with the ePTFE inner tube.

No *prima facie* showing of obviousness has been established because the combination fails to produce all of the features recited in independent claims 1 and 20, namely, a stent in direct contact with the inner tubular member.

Furthermore, in the embodiment disclosed by Banas et al. wherein the outer tubular member is excluded, the polymer clad wire winding is shown in an overlapping pattern as opposed to the recitation in Applicant's claims 1 and 20 wherein the tape is wound in a non-continuous manner. See FIGS. 13 and 14 of Banas et al. reproduced below:



Thus, in either embodiment wherein the tubular member is either included or excluded, the Banas et al. device results in a continuous outer layer of PTFE.

Therefore, it is Applicant's position that either the outer tubular member of Golds et al. is included in the assembly or the polymer clad wire winding is wrapped about the inner tube in a continuous manner.

CONCLUSION

Reversal of the rejection of claims 15, 16 and 18-23 under 35 U.S.C. §103(a) as being obvious over Golds et al. (US Patent 6,001,125) in view of Banas et al. (6,264,684) is respectfully requested. The attorney of record may be reached at (952)563-3011 to resolve any issues which may expedite prosecution of this application.

Respectfully submitted,

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Date: March 17, 2010

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